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VIA COURIER

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004D-0343
Comments on Draft Guidance "Hospital Bed System Dimensional Guidance to Reduce Entrapment"

Dear Sir or Madam:

King & Spalding LLP offers the following comments as the Food and Drug Administration ("FDA") considers recommendations for manufacturers of hospital beds and hospital bed accessories.

For reasons set forth below, we believe FDA has acted contrary to law and its own regulations in publishing the Draft Guidance entitled "Hospital Bed System Dimensional Guidance to Reduce Entrapment" ("Draft Guidance"). In its rush to publish, FDA failed to undergo Notice and Comment rulemaking, failed to take into consideration the Hospital Bed Safety Workgroup (HBSW)'s recommendations and violated its own Good Guidance Practices ("GGPs").

I. FDA's Draft Guidance Constitutes Rulemaking and Thus is Subject to Notice and Comment Provisions of the Administrative Procedures Act.

FDA's Draft Guidance is rulemaking in the disguise of a Guidance Document, and as such should have been issued only after the agency undertook Notice and Comment rulemaking procedures in accordance with the Administrative Procedures Act ("APA"). Courts have long recognized the importance of statutorily prescribed procedures in the Administrative Procedures Act. *See, e.g. California Canners & Growers Assoc.*, 7 Cl. Ct. 69, 81-84 (U.S. Cl. Ct. 1984) (noting importance of opportunity for interested parties to comment on proposed rulemaking).

Section 553 of the APA requires substantive agency rules to be issued only after undertaking Notice and Comment procedures, except when the agency is merely adopting an "interpretive rule" or a "general statement of policy." *See* 5 U.S.C. §553(b)(3)(A). Although the APA does not define the term "substantive," courts have generally recognized that substantive rules "create new law, rights, or duties," with the force of law, while interpretative rules clarify, rather than create, law. *See White v. Shalala,* 7 F.3d 296, 303 (2d Cir. 1993); *see also Pereles v.*

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Sullivan, 948 F.2d 1348, 1354 (2d Cir. 1991). As the court in *Syncor Int'l Corp.* v. *Shalala*, 127 F.3d 90, 95 (D.C. Ct. App. 1997) explained,

> A substantive rule has characteristics of both the policy statement and the interpretive rule; it is certainly in part an exercise of policy, and it is a rule. But the crucial distinction between it and the other two techniques is that a substantive rule *modifies* or *adds* to a legal norm based on the agency's *own authority.*

(emphasis in original).

This Draft Guidance constitutes a substantive rule that is subject to Notice and Comment rulemaking because it creates, rather than clarifies, law. FDA is using its *own authority* to add a legal norm--a substantive performance standard that hospital beds, Class I and Class II devices, must be configured to specified dimensional criteria in order to avoid entrapment. *See* Draft Guidance at 1. Clearly, FDA's Draft Guidance is not an interpretative rule:

> It does not purport to construe any language in a relevant statute or regulation; it does not interpret anything. Instead, FDA's rule uses wording consistent only with the invocation of its general rulemaking authority to extend its regulatory reach.

Syncor Int'l Corp., 127 F.3d at 95.

As the court in *Bellarno Int'l v. FDA*, 678 F.Supp. 410, 415 (E.D.N.Y. 1988) stated, just because a document "is entitled 'guidance' by the agency does not mitigate the tone of the language that follows its title." *Id. See also Caribbean Produce Exch. v. Sec'y of HHS*, Food Drug Cosm. L. Rep. (CCH) (Puerto Rico 1988), (holding that it was inappropriate for FDA to publish a "guideline" for allowable levels of imported foods because FDA did not follow Notice and Comment rulemaking procedures).

In the same manner, FDA's "*Guidance*" is a "guidance" in name only--it sets a performance standard by requiring manufacturers of particular product codes to use "maximum and minimum dimensional limits of gaps or openings in hospital bed systems"[1]. Draft Guidance at 7. Therefore, FDA's "Guidance," dictating how a product must perform, is a substantive rule, and as such should be subject to Notice and Comment rulemaking.

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[1] Specifically, FDA "recommends" that manufacturers of all devices with Product Codes FMR, FNJ, FNK, FNL, FPO, IKZ, ILK, INK, INY and IOQ use the dimension criteria set forth in the Draft Guidance. *See* Draft Guidance at 5.

II. FDA's Draft Guidance Inappropriately and Unnecessarily Instills Fear in Consumers.

We urge FDA to engage in a fair and balanced review before proceeding to set performance standards for hospital bed systems. This is not to suggest that we do not support FDA's efforts to address hospital bed safety--however, we do expect FDA to engage in a thorough and scientific analysis before issuing performance standards in this area.

A. Entrapment is not a Statistically Significant Problem.

FDA's rush to publish a hastily-written Draft Guidance is unnecessary given the low number of entrapment reports. According to the Draft Guidance, FDA has received only 575 entrapment reports over the past nineteen years--and 106 of those reports did not result in injury. That figure--over a period of almost two decades--is astoundingly small given the millions of patients who are in hospital beds every year. By any scientific measure, that figure is statistically insignificant, and does not warrant FDA's "rush to publish."

B. Graphic Drawings are an Inappropriate "Scare Tactic" for a Scientific Guidance

We request that FDA remove its detailed drawings of entrapped patients from the Draft Guidance. FDA's drawings of people caught in various positions are unnecessarily gruesome and wholly inappropriate for a Draft Guidance. *See, e.g.,* Draft Guidance at Appendix D. These drawings are in no way objective, as there are numerous, more appropriate ways to illustrate the zones. For example, the schematic drawing of the hospital bed and the zones in the Draft Guidance fully illustrate all possible entrapment areas. Alternatively, the "stick figure" representation of an entrapped patient also clearly illustrates the problem--without relying on dramatization and fear tactics. *See* Draft Guidance at 11.

III. FDA Has Violated Good Guidance Practices by Failing to Include Test Method and Design Validation Criteria.

FDA is required to follow Good Guidance Practices ("GGPs") when developing a guidance document. *See* 21 C.F.R. §10.115(e) (*stating* "[t]hese GGPs must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad audience"). In this case, FDA has created "regulatory expectations" that are not only "not readily apparent," but are *patently unreasonable* given the absence of test methods in this Draft Guidance.

FDA requires manufacturers of Class II-III medical devices (which encompasses hospital beds) to use design verification and validation:

> Each manufacturer of any class II or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

21 C.F.R. §820.30. However, FDA has failed to provide validated test methods *for all seven of its proposed zones.* FDA is not holding itself to the same standard it holds industry by failing to include any validated test methods. Moreover, manufacturers have no way of knowing whether or not they are in compliance with the Draft Guidance because they have no test methods to confirm whether their specific bed system complies with the Draft Guidance. FDA is not engaging in GGPs by offering a standard without offering a test method for measuring compliance.

IV. FDA's Approach is Not the "Least Burdensome"

FDA claims that its Draft Guidance

> reflects our careful review of what we believe are the relevant issues related to reducing hospital bed entrapment and what we believe would be the *least burdensome* way of addressing these issues.

Draft Guidance at 2 (emphasis added). "Least burdensome," according to FDA, is defined as "a successful means of addressing a pre-market issue that involves the most appropriate investment of time, effort, and resources on the part of industry and FDA." Final Guidance: The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concepts and Principles (October 4, 2002) at 2.

Contrary to its claim, FDA cannot claim this Draft Guidance is a "least burdensome" effort for the reasons discussed below.

A. FDA Improperly Did Not Wait for HBSW's Forthcoming Recommendations

FDA has improperly published this draft guidance before receiving final recommendations from its Hospital Bed Safety Workgroup ("HBSW"). The HBSW was formed *at the request of FDA* to fully examine entrapment problems and issue recommendations to improve patient safety associated with the use of hospital beds. *See* Draft Guidance at 3. The HBSW, in conjunction with industry, has invested a major amount of time, effort and resources--it has spent several years designing properly validated test methods to prevent entrapment.

However, the Draft Guidance has disregarded HBSW's efforts and failed to include any tools or test methods that HBSW has thus far investigated.

In order to fulfill its "least burdensome" promise, FDA should incorporate HBSW's tools and properly validated test methods, once finalized, into its performance standards. However--we again note that FDA has a duty to only incorporate HBSW's recommended tools and test methods *after* engaging in Notice and Comment Rulemaking.

B. The Draft Guidance Includes Zones With No Reported Entrapments.

Several of the "zones" identified by FDA have had few or zero reports of entrapment. For example, the Hospital Bed Safety Workgroup (HBSW), in meetings over the past three years, decided to abandon Zones 5 and 6 from the measurement process because there have been so few reports. Moreover, by its own admission, FDA has had zero reports of entrapment for Zone 7. *See* Draft Guidance at 22 (stating "[t]he adverse event report descriptions do not clearly identify entrapments as having occurred in zone 7"). If FDA chooses to include Zones 5,6, and 7, it should support the additions with evidence that a significant risk exists in these zones. Lastly, FDA's addition of Zones 5, 6, and 7 is particularly problematic in light of the fact that no test methods have even been investigated (by FDA or HBSW) for these zones.

We recommend that in order to truly seek the "least burdensome" approach, the Final Guidance give careful consideration to HBSW's findings that Zones 5, 6 and 7 are unnecessary.

C. "Retroactive application" Results in a Significant Burden.

FDA's Draft Guidance applies to devices "that have been manufactured prior to this guidance." Draft Guidance at 5. Although FDA does not plan to take "enforcement actions that involve 'corrections and removals'" against bed systems currently in the marketplace, it does require hospitals to "implement adequate design controls" on these pre-existing hospital bed systems. *See* Id. The problem with FDA's requirement is that FDA itself has failed to define "adequate design controls" in this guidance--which will result in a wide variance between hospitals of the performance standards for these beds.

Furthermore, requiring hospitals to upgrade beds currently in their possession is a significant financial burden. Hospitals will need to employ skilled workers to conduct these upgrades, as well as pay for cost of materials and time. This upgrade will result in a substantial expense to hospitals across the country.

Given the relatively small number of entrapments that have occurred in the past two decades, we recommend that FDA implement a voluntary "phase-out" plan, wherein new bed

systems purchased by hospitals (on an "as-needed" basis) comply with the performance standards (as finalized after Notice and Comment rulemaking).

V. The Draft Guidance Fails to Achieve the Goal of Global Harmonization

In the 1997 Food and Drug Modernization Act ("FDAMA"), Congress mandated that FDA must attempt to harmonize regulatory requirements with global standards in an effort to reduce the burden on manufacturers. FDAMA requires FDA to make

> efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

FDAMA § 410 (1997).

Despite this directive, FDA has published a Draft Guidance with noteworthy differences from the international standard, IEC 6061-2-38 ("IEC standard"). If FDA finalizes this Draft Guidance "as is," manufacturers will have two different standards for a product sold world-wide. Requiring manufacturers to juggle two different standards is not the "least burdensome" approach, and moreover thwarts FDAMA's mission of global harmonization. We recommend that FDA utilize HBSW's forthcoming recommendations, which are in line with IEC standards, in order to achieve a minimal burden on manufacturers while maximizing patient safety.

VI. Conclusion

While we recognize that the issue of hospital bed system safety deserves attention, we urge FDA to focus it's attention in a more objective, thoughtful manner. Public health is not served by a hastily-drafted guidance. Rather, FDA should follow the lead of the HBSW, who have diligently and carefully been crafting a solution to the problem of entrapment. FDA should (1) use HBSW's forthcoming final recommendations and (2) provide opportunity for Notice and Comment on these recommendations.

We hope you find these comments useful. If you have any questions, please contact me at (202) 626-2903.

Regards,

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